University of Pittsburgh

Graduate School of Public Health
Department of Environmental and Occupational Health

130 DeSoto Street
Pittsburgh, Pennsylvania 15261
412-624-3155
Fax: 412-624-3040

MEMORANDUM

TO: JCCRER Executive Committee

JCCRER Scientific Review Group

DOE Office of International Health Programs, EH-63

CC: Dr. Ron Filipy, US PI of Project 2.1

Dr. Ethel Gilbert, US PI of Project 2.2

Dr. Lynn Anspaugh, US PI of Project 2.4

FROM: US Team, Project 2.3 /Niel Wald, P.I.

DATE: March 1, 1997

RE: Observations and Recommendations Concerning Direction 2 Projects

---

The purpose of this memorandum is to share some of our observations that stem from the Feasibility Study that comprised the first year's effort on JCCRER Project 2.3. Inasmuch as these observations go beyond the specific findings, conclusions and recommendations of the final report of our Feasibility Study and deal with matters involving the other projects under Direction 2, we have elected to call them to your attention by means of this memorandum.

The importance of the Mayak worker population to the field of radiation protection must not be underestimated. The variety of radiation exposure situations including qualitative differences in radiation types and combinations, and quantitative differences in dose rates and exposure magnitudes, the retention of records and the long duration of the follow-up observations make this occupational cohort a unique resource for improving our understanding of external and internal protracted exposure effects over a wide range of dose rates. The information contained in these records, *if developed by well-designed scientific studies*, provides an important opportunity to test the assumptions and extrapolations which underlie current radiation risk assessments and radiation control

regulations using newly available and more relevant data. However, there are two particular methodological issues that have emerged from the Feasibility Phase of Project 2.3 that need to be explicitly addressed by JCCRER because of their implications for the scientific validity of all the Direction 2 projects. These issues concern, first, the definition of the Mayak worker population and, second, the quality control procedures applied to the assessment of occupational exposure records.

Mayak Worker Population Definition

A number of studies of the Mayak radiation worker population have already been performed and published by our Russian colleagues: others are now in progress or proposed collaboratively. *We were unable to find any indication of the existence of or a plan for a single and complete Master File with a unique identifier for each past and present member of this work force.* The creation of such a complete Master File would be important for a number of reasons:

- It would assure that all of the observations on any individual could ultimately be linked and that dosimetric data are the same in each project in which that person might be studied.
- It would serve as a unified "sampling frame" or "sampling universe"; this is a methodological prerequisite for the unbiased selection of random samples of workers from the total population.
- It would end the confusion engendered by the apparent existence of a number of separate data bases already developed by different groups of Russian investigators. This would also avoid a duplication of effort, while facilitating longitudinal studies and not detracting from individual investigations with different objectives and endpoints.

It took seven years for the participants in the Atomic Bomb Casualty Commission to learn the absolute necessity of a unified Master File of the entire study population. With that example in mind, a similar Master File was developed for the population living within five miles of the TMI-2 reactor within 6 months after the accident. We are in a position to apply what these predecessors learned near the outset of these projects in Direction 2. Indeed, we would be hard put to justify its omission now.

Quality Control Procedures for Exposure Record Assessment

The best possible external and internal exposure estimation is a crucial aspect of all the Mayak worker studies. The biomedical findings of these studies can only be of real use if reliable dose-response information can be generated and analyzed. The potential availability of historical measurement data, along with the some of the actual dosimetry films and bioassay materials, could provide a substantial improvement over the A-bomb survivor dosimetry situation. However, we are concerned that *the need for quality assurance/quality control (QA/QC) procedures requiring direct collaborative access by US*

investigators to the original dosimetry records as well as films and bioassay materials (where available) has not as yet been fully recognized in the design of the Direction 2 projects. We would strongly recommend that the original Mayak dosimetry records (and, perhaps, the original films and bioassay materials, where available) be critically evaluated by the US and Russian collaborators using an objective, statistically-based and quantitative Quality Assurance/Quality Control (QA/QC) methodology similar to the one implemented for the FIB-1 biomedical records in the Project 2.3 Feasibility Study. This QA/QC methodology is described in a detailed fashion in the Final Report of the Project 2.3 Feasibility Study (March 1997) and in the Report on the QA/QC Component of the study' dated December 19, 1996. This recommendation will require a major US and Russian commitment to suitable research designs, close bilateral involvement and objective performance measures in order to justify the biomedical and epidemiological investment involved in the Direction 2 projects.

Implementation of Recommendations

Human nature being what it is, and with several different US funding agencies as well as several different Russian organizations and working groups, the above recommendations may not be easy to implement. A greater level of knowledgeable and unified oversight will be required to assure that all the participants and their projects add up to a credible, well focused research program. However, if this rare opportunity to add to our ability to live in the Nuclear Age is not to be wasted, such a major implementation effort is justified and necessary.